

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

SHEENA DORMAN, *et al.*

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Plaintiffs

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CIVIL ACTION NO. MJG-15-1102

vs.

*

ANNE ARUNDEL MEDICAL CENTER,
et al.

*

*

Defendants

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**DEFENDANTS' MOTION TO PRECLUDE OPINION TESTIMONY OF
ROBERT ALLEN, Ph.D. AND REQUEST FOR HEARING**

Defendants Annapolis OB/GYN Associates, P.A. and Richard G. Welch, M.D. (collectively "Defendants"), move pursuant to Fed. R. Evid. 702 and controlling law to preclude the testimony of Plaintiffs' biomechanical engineer rebuttal expert, Robert Allen, Ph.D.

Dr. Allen's causation opinions do not meet Rule 702's threshold requirements of reliable scientific principles and methods. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Dr. Allen advocates that Plaintiff B.M.'s persistent neonatal brachial plexus palsy (NBPP) can be caused only by excessive physician-applied traction—a position that inexplicably contradicts the established consensus of the relevant scientific community. It is widely recognized that maternal forces of labor also cause injury to the brachial plexus. Dr. Allen purports to divine how Dr. Welch delivered B.M., contrary to the evidence and Dr. Welch's testimony. He even opines that B.M. would not have a brachial plexus palsy if Dr. Welch had delivered Plaintiff by some unspecified maneuver, other than the McRoberts maneuver. Dr. Allen's opinion is scientifically unsound and likely to confuse and mislead the jury. Under *Daubert*, it must be precluded.

For these reasons, as set forth here and in the accompanying Memorandum of Law, Defendants move this Honorable Court for an Order precluding the testimony of Plaintiffs' biomechanical engineering rebuttal expert, Robert Allen, Ph.D.¹

Respectfully submitted,

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¹ To the extent that any of Plaintiffs' other experts such as Scott Kozin, M.D. and Fred DuBoe, M.D., base their causation opinions solely on the existence of the NBPP (that is, that it could only have occurred from excessive lateral traction applied by a physician), and ignores other evidence, the opinion suffer from similar defects to Dr. Allen's opinions and should also be excluded under Rule 702.

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**DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN
SUPPORT OF MOTION TO PRECLUDE OPINION TESTIMONY OF
ROBERT ALLEN, Ph.D. AND REQUEST FOR HEARING**

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I. INTRODUCTION

Dr. Allen wants to offer the jury an outdated causation theory that the relevant scientific community rejects: in the absence of fetal pathology, brachial plexus injuries occur during childbirth *only if* care providers pull too hard on the baby's head. This hypothesis has been disproven. An authoritative 2014 monograph on neonatal brachial plexus palsy by ACOG,² the leading professional body in the field of obstetrics and gynecology, and dozens of peer-reviewed articles have rejected this theory. Instead, they show that maternal expulsive forces pushing a fetus's shoulder against the maternal bony pelvis can, by themselves, or in conjunction with typical delivery, cause a neonatal brachial plexus palsy.

Dr. Allen, who has no medical expertise, bases his opinion on a hodgepodge of unreliable and often outdated studies on the nature of the forces applied during a live childbirth. From these studies, he then extrapolates conclusions that the same studies do not support. Dr. Allen fails to seriously address or distinguish the relevant scientific literature and studies, including the numerous peer-reviewed scientific studies that Defendants' biomechanical engineering expert, Dr. Michelle Grimm, relied on. Dr. Allen's opinion lacks the reliability that *Daubert* requires.

Dr. Allen's opinions also do not "fit" the evidence. He does not account for B.M.'s low muscle tone at birth – a factor even he recognizes makes a fetus more susceptible to injury from stretch of the nerves. He also ignores the possibility that the left arm may have been in the posterior

² American College of Obstetricians and Gynecologists, "Neonatal Brachial Plexus Palsy" (2014) (hereafter referred to as the "ACOG Monograph"), attached as Exhibit 1. This publication has been endorsed by the American Academy of Pediatrics, the American Academy of Physical Medicine and Rehabilitation, the American College of Nurse-Midwives, the American Society for Reproductive Medicine, The Child Neurology Society, the Japan Society of Obstetrics and Gynecology, The Society for Maternal-Fetal Medicine (*see* <https://www.smfm.org/publications/164-acog-task-force-report-on-neonatal-brachial-plexus-palsy>), The Society for Obstetricians and Gynaecologists of Canada, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (*see* https://www.ogmagazine.org.au/wp-content/uploads/2017/07/OGAutumn2014_web.pdf).

position during delivery – leading to a type of stretch that clinical studies show occurs before any clinician traction is applied.

Dr. Allen's opinions against Dr. Grimm and Defendants' other experts are likewise based on unreliable extrapolations from outdated and inapposite scientific publications that contradict the well-established consensus of the scientific community. Further, several of his opinions rebutting Defendants' physician experts stray into discussing the standard of care, an area which Dr. Allen, by his own admission, is not qualified to offer expert testimony.

II. BACKGROUND

Sheena Dorman and Dillon Ming filed a medical malpractice action against the Anne Arundel Medical Center, Annapolis OB-GYN Associates P.A. and Dr. Welch alleging that their son's left neonatal brachial plexus palsy ("NBPP") was caused by negligence. NBPP, which can be transient or permanent, results from a stretch of the nerves in the area of the shoulder (brachial plexus). It occurs in roughly 1.5 per 1000 total births.³ Although commonly associated with shoulder dystocia, which is an event occurring in the course of delivery when a fetal shoulder impacts on the mother's bony pelvis and prevents delivery of the baby, more than half of NBPP occurs without shoulder dystocia - roughly 0.9 per 1000 total births. *Id.* at 2.

During Sheena Dorman's labor and delivery, the baby encountered a brief shoulder dystocia. Shoulder dystocia is most often defined as a delivery that requires additional obstetric maneuvers following failure of gentle downward traction on the fetal head to effect delivery.⁴ Shoulder dystocia is an obstetrical emergency, as it can lead to interruption of the fetal oxygen supply and can potentially lead to brain damage or even death. *Id.*

³ Exh. 1, ACOG Monograph, at 1.

⁴ Exh. 2, ACOG Practice Bulletin No.40 ("Shoulder Dystocia"), at 1 (2002, reaff'd 2008). Although clinicians may suspect a shoulder dystocia from a number of factors, it "is not formally diagnosed until a trial of downward axial traction has been unsuccessful in delivering the anterior shoulder." *Id.*

During the delivery of B.M., Dr. Welch relieved the shoulder dystocia with the McRoberts maneuver (pulling the mother's legs up to her chest),⁵ a maneuver used to reduce the force needed to achieve delivery and the resulting stretch to the brachial plexus.⁶ The total time for the delivery was 30 seconds.⁷ The medical record does not describe the position of the baby at delivery, and therefore it is unknown which of the baby's shoulders was anterior, or front, and which was posterior, or back. B.M. weighed 4810 grams at birth. He had very low Apgar scores for muscle tone (0 for tone at one minute and 1 for tone at five minutes, respectively) immediately after birth. No spontaneous movement was noted in B.M.'s left arm, and a possible Erb's palsy was diagnosed.

Although the medical record does not describe the degree of traction and Dr. Welch testified that he applied gentle traction in an axial plane,⁸ Plaintiffs nonetheless assert that the traction applied was "excessive," *See* Pl.'s Compl. at 3, 6-7, and that B.M.'s Erb's palsy was the result of excessive traction in the delivery.⁹

A. Robert H. Allen, Ph.D.

Dr. Allen has never delivered a baby.¹⁰ Or at least, "not a real one." *Id.* He is not a physician. He never attended medical school. *Id.* at 36. He makes no pretense of being qualified

⁵ *See* delivery note, attached as Exh. 3.

⁶ *See e.g.*, Exh. 4 Gherman, et al., "The McRoberts' Maneuver for the Alleviation of Shoulder Dystocia: How Successful is it? 176 Am. J. Obstetrics and Gynecology, 656-61 (1997).

⁷ Exh. 3 (delivery note).

⁸ Depo. of Dr. Richard Welch, at 81, 83-84. Relevant portions of Dr. Welch's deposition are attached as Exh. 5.

⁹ Erb's Palsy is a form of neonatal brachial plexus palsy involving stretch injury to certain nerve roots found in the neck. *See* Exh. 1, ACOG Monograph at 1.

¹⁰ Depo. of Dr. Allen, at 37. The transcript of Dr. Allen's deposition is attached in full as Exhibit 6.

to opine about the standard of care for physicians.¹¹ *Id.* Rather, Dr. Allen is an engineer¹² who develops shoulder dystocia simulators. Although he purports to divine the amount of force used in the delivery of B.M. relative to forces used in “normal” delivery, he does not recall ever measuring the amount of upward or downward traction used in a “normal” delivery. *Id.* at 128. And he has never done maternal uterine force measurements. *Id.*

Dr. Allen was identified ostensibly to “rebut” the causation testimony of the defense experts, including (according to his report) Dr. Michelle Grimm, Dr. Suneet Chauhan, Dr. Craig Dickman, Dr. Nancy Hammond, Dr. Kenneth Silver, and Dr. Stephanie Greene.¹³ The majority of his “rebuttal” opinions address the opinions of Dr. Michelle Grimm, a Professor of Biomedical Engineering at Wayne State University and the Program Director, Biomedical Engineering Program at the National Science Foundation.¹⁴ She specializes in the field of brachial plexus and other birth injuries and has won numerous awards for her research in the field, including awards from the Society of Maternal Fetal Medicine for her work in using computer modeling software to assess the forces that affect a fetus during a shoulder dystocia delivery. *Id.*¹⁵

¹¹ While Dr. Allen admits that he is not qualified to offer standard of care opinions, many of his opinions are standard of care opinions dressed up as causation opinions. He opined, for example, that Dr. Welch used traction “far in excess ... of that normally used” and purported to opine about how much force obstetricians apply in a “routine” delivery. *See* Report of Dr. Robert Allen, Dec. 29, 2016, at 5 (attached in full as Exhibit 7). Opinions about what obstetricians “routinely” do and whether traction was “excessive” communicates to the jury views about what was reasonable under the circumstances – precisely what Dr. Allen admits he is not qualified to do.

¹² Dr. Allen teaches at Johns Hopkins University but has never applied for tenure. Exh. 6, Depo. Of Robert Allen at 126. He was denied tenure at the University of Delaware in 1996 because the University viewed the quality of his teaching as “not being excellent.” *Id.* at 19-20.

¹³ Exh. 7, Dr. Allen’s report at 6-10.

¹⁴ *See* Exh. 8, Dr. Grimm’s CV.

¹⁵ Based on her review of the relevant records and transcripts in the case, Dr. Grimm concluded that “the cause of [B.M.’s] brachial plexus injury was due to stretch to the nerve complex caused by differential motion of his head and torso as his left shoulder came into contact with Ms. Dorman’s bony pelvis... With the contact of [B.M.]’s shoulder with the bony pelvis, stretch occurred to the nerve that was sufficient to cause his residual injury as a result of maternal expulsive forces, alone or in combination with normal amounts of axial traction.” Report of Dr. Michelle Grimm, attached as Exhibit 9, at 4. Dr. Grimm cited to computer model and animal studies, studies which were discussed and relied upon in the 2014 ACOG

Dr. Allen's opinions are based in part on mathematical calculations, but his characterization of his calculations is fuzzy. For example, Dr. Allen claimed that a study showed a 400% reduction in the incidence of NBBP¹⁶ before eventually conceding the reduction claimed by the study was actually much smaller.¹⁷

Dr. Allen offered the following summation of his opinions, presumably intended to be expressed at trial:

The sole cause of BM's permanent brachial plexus injury in his left arm was Dr. Welch's downward lateral traction to the head during the 30-second head-to-body interval of the shoulder dystocia delivery. The lateral traction was seven to eight times that normally used. There is no clinical evidence for any other etiology for

Monograph, in support of her opinion. *Id.* And, she drew upon the medical records and deposition testimony, including testimony that Dr. Welch applied only gentle axial traction, and B.M.'s low muscle tone at birth, making him more susceptible to stretch.

¹⁶ Compare Dr. Allen's assertion that the incidence of brachial plexus injury has been reduced at all (whether by 400% or 75%) with a literature review identifying no change in the incidence. Exh. 10, H.F. Sandmire, et al, "Controversies Surrounding the Causes of Brachial Plexus Injury," 104 Int. J. of Gyn. and Obstetrics, 9-13 (2009).

¹⁷ Exh. 6, Depo. of Robert Allen at 31-33:

Q That's actually more of a 75 percent reduction, isn't it? I mean if you went from 491 to zero, that would be a 100 percent reduction, right?

A No.

Q Then how do you get from, if you go from 100 percent to zero how is that not a 100 percent reduction?

* * *

A. When something is reduced by a factor, each factor is a hundred percent. So if you go from a hundred to 50, that's a hundred percent, a hundred percent reduction.

Q A factor of what? If you cut something in half, it's a 100 percent reduction?

A No. It's a 50 percent reduction.

Q Okay. And so in order to get a 100 percent reduction you would have to eliminate it entirely?

A When you get to zero it's a little tricky, but.

Q So if you go from, let's just say 491 down to a number like 123, that would be roughly a 75 percent reduction, right?

A Yes, it would be about a quarter.

Q Is there any literature --

A Which would be a 400 percent reduction, so.

Q Okay. If you're --

A It's a term, right? So let's say you have 500 instead of 491.

Q Okay. If you cut it in half, that's a 50 percent reduction?

A No, no, we're not disagreeing with that. I agree with you that's a quarter. Okay?

Q If you go to a quarter, then that's about a 75 percent reduction?

A Yes

this permanent injury; uterine forces nor the shoulder dystocia itself did not cause or contribute to this injury. BM's shoulder dystocia could have been resolved without permanent injury if the McRoberts maneuver would have stopped after routine traction, and a fetal maneuver was attempted.¹⁸

To come up with numbers for "peak traction" and traction "normally used," Dr. Allen used data derived from "sensor gloves" studies (one of which he co-authored) that attempted to measure forces applied during delivery by placing sensors on the delivering physician's right hand. These studies directly measured only the contact forces in the physician's hand and not the traction applied to the fetal head. The lead study also looked at only a single physician. Using that questionable method, Dr. Allen then selected a number in the middle of a range of presumed traction forces and proclaimed it to be an average without ever calculating an average. Indeed, he admitted that he never even looked at the distributive range to be able to calculate an average.

A Most, most normal deliveries happen between zero pounds of traction and 10 pounds of traction. The average being about five pounds of traction.

* * *

Q. That would assume that they are equally distributed among zero and 10. Is there any basis that you have to cite for that?

A Actually, I don't think I've, I've looked at that.

Q Okay. So, for example, if you had 99 deliveries that happened with 9 pounds of traction, and one that happened at 1 pound of traction, that would still be a hundred deliveries between zero and 10, but the average would be far greater than 5, right?

A Yes, that would be true.

* * *

Q So you really don't have any basis other than simply taking a mid point between zero and 10 to say that the average is 5?

A Yes.¹⁹

In other words, Dr. Allen simply took the high number (10 pounds) of average axial force stated in the sensor gloves studies as sufficient for a "routine" delivery and the lowest amount (0 pounds)

¹⁸ Exh. 7, Dr. Allen's report at 10. Arguably this testimony is not in the nature of true rebuttal, as the burden of establishing a causal nexus between any alleged negligence and the Erb's palsy is necessary to establish Plaintiffs' *prima facie* case.

¹⁹ Exh. 6, Depo. of Robert Allen at 70-74 (emphasis added).

and assumed, without any basis or definition, that a “routine” delivery generally involves the midpoint between the two figures, or around five pounds of force. This assumption is scientifically and mathematically unsound.

Dr. Allen next compared the speculative five-pound “normal” figure that he had estimated to the amount of force that he believes to be necessary to cause nerve rupture. He suggests nerves may stretch or rupture when they are stretched at least 30 percent, which in his view requires the application of at least 35 to 40 pounds of lateral force. *Id.* at 127. That estimate was likewise derived from figures from outdated and unreliable studies, which Dr. Allen himself admitted do not follow current biomechanical techniques. *Id.* at 47-49.

In essence, Dr. Allen derived his opinion by simply dividing his view of the peak force necessary to cause a NBPP injury (35 to 40 pounds) by his estimate of the “average” or “normal” force applied during an uncomplicated delivery, 5 pounds, to conclude that Dr. Welch must have applied 7 to 8 times the “normal” delivery force. *Id.* at 79-80. Dr. Allen’s “methodology” of extrapolating speculative “normal” force values from unreliable sensor gloves studies that cannot be replicated,²⁰ deriving an “average” of those forces without even looking at their distribution, and then comparing those values against estimates of the force necessary for nerve rupture derived from other concededly unreliable studies is unscientific and speculative. Dr. Allen’s opinions do not meet the requirements of *Daubert* and Rule 702 and are not admissible.

B. The Science

In 2011, The American College of Obstetricians and Gynecologists, an organization comprised of more than 58,000 obstetrician/gynecologists in the United States,²¹ convened a task

²⁰ See affidavit of Suneet P. Chauhan, M.D., describing two years of unsuccessful efforts to replicate Dr. Allen’s work, attached as Exhibit 11.

²¹ <https://www.acog.org/About-ACOG/About-Us> (retrieved March 11, 2018)

force “[t]o review and summarize the current state of the scientific knowledge, as set forth in the peer-reviewed and relevant historical literature, about the mechanisms that may result in neonatal brachial plexus palsy” in a manner that would “serve as a resource” for health care providers.²² The results of that study were published in 2014 in a monograph entitled “Neonatal Brachial Plexus Palsy” (“the ACOG Monograph”). Among other things, the ACOG Monograph identified scientific studies addressing the causes of NBPP: “What is known at this time with reasonable medical certainty is that NBPP occurs infrequently and can be caused by maternal (endogenous) forces or clinician-applied (exogenous) forces or a combination of both. . .” *Id.* at xvii

1. *Causation of Brachial Plexus Palsies*

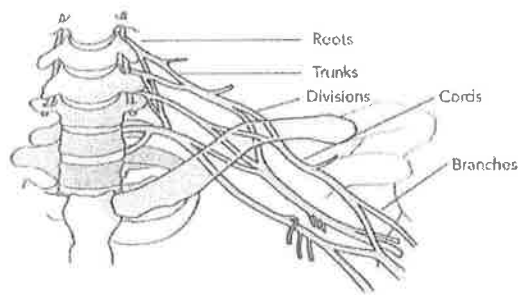


Figure 5-1. Schematic diagram of the brachial plexus. 

The brachial plexus is a complex structure [*see* figure 5-1] located in the neck and shoulders that connects spinal nerves to their terminal branches in the upper arm. *Id.* at 51. A neonatal brachial plexus palsy “presents in a newborn as a weak or paralyzed upper extremity, with the passive range of motion greater than the active.” *Id.* at 1. NBPP can be temporary or persistent, meaning continuing dysfunction for twelve or more months. *Id.*

²² Exh. 1, ACOG Monograph at xi (2014). Dr. Grimm was invited to be a part of the task force that helped to prepare the report, along with other prominent experts in obstetrics and gynecology, maternal-fetal medicine, and other disciplines.

Several factors have been associated with NBPP. Of significance to this case, poor muscle tone, which results in less resistance to applied forces, has been found to predispose a neonate to a brachial plexus stretch injury.²³ Thus, B.M.'s very low Apgar scores of 0 and 1 for muscle tone at birth indicate that he was a baby predisposed to NBPP.²⁴

a. Biomechanics of Delivery

A normal vaginal delivery will involve the application of both maternal forces of labor, including uterine contractions and other natural physical events, as well as a traction from a delivering physician.²⁵ A leading obstetrics textbook by Gabbe et al. emphasizes the role of appropriate physician traction to effectuate delivery in a normal, uncomplicated labor: “[W]hen the fetal head crowns and delivery is imminent, gentle pressure [from the delivering physician] should be used to . . . control delivery, potentially protecting from perineal injury.”²⁶ Thereafter, the baby’s anterior shoulder “should then be delivered by gentle downward traction in concert with maternal expulsive efforts[,]” followed by the posterior shoulder. *Id.*

During labor, a baby’s shoulders “must pass at least two bony structures that can impede forward motion—the sacral promontory in the posterior aspect of the birth canal and the symphysis pubis on the anterior side.”²⁷ Differential motion of the baby’s head or torso during labor can bring the shoulders into contact with either or both of these two bony pelvic structures. As the baby progress through the pelvis, one shoulder is anterior, meaning it is more forward or “up” in a schematic diagramming the delivery, and the other is posterior, or “down.” Either or both shoulders can become “stuck” on the bony pelvis – i.e., a shoulder dystocia – during delivery.

²³ *Id.* at 3; *see also* Exh. 12, Joyner et al., “Brachial Plexus Injury,” 27 *Pediatrics in Review* 238 (2006).

²⁴ *See* Exh. 9, Dr. Grimm Depo. at 52, 109.

²⁵ Exh. 1, ACOG Monograph at 23.

²⁶ Exh. 13, Gabbe et al., *Obstetrics: Normal and Problem Pregnancies*, 281 (6th Ed. 2012).

²⁷ *See* Exh. 1, ACOG Monograph at 27.

b. Biomechanics of Shoulder Dystocia

When a fetal shoulder is restrained, either before or after the head delivers, maternal contractions and pushing will continue to apply force to push the fetal head and neck forward. “[W]hen one of the shoulders is restrained by the bony pelvis, any forces that continue to advance the head and neck will cause a stretch in the brachial plexus.” *Id.* at 27.

1. Posterior shoulder dystocia

“Contact between the posterior shoulder and the sacral promontory occurs before the head delivers[,]” and thus, prior to any traction or force being applied to the head by the clinician during delivery (and before the clinician could diagnose or evaluate such an impaction). *Id.*

2. Anterior shoulder dystocia

Contact between the anterior, or outward-facing, shoulder and the symphysis pubis “typically occurs as the head delivers over the perineum. As the anterior shoulder impacts the symphysis, the head and neck will advance as a result of the next retraction and may retract back on the perineum.” *Id.* Clinicians refer to this head-neck retraction as a “turtle sign.” *Id.*

3. Necessity of Rapid Delivery During Shoulder Dystocia

Once the baby’s head delivers but the baby’s body does not, the baby is at significant risk of hypoxic injury leading to brain damage, including “birth asphyxia and subsequent neonatal hypoxic-ischemic encephalopathy,” a devastating form of brain injury. *Id.* at 47. Permanent neurologic brain injury can occur as rapidly as two minutes after shoulder impaction. *Id.* Thus, “[a] pragmatic approach in all deliveries involving shoulder dystocia [is] to minimize delay in delivery as much as possible by implementing appropriate maneuvers” – including the use of traction to deliver the baby – once shoulder dystocia is diagnosed. *Id.*

c. Clinician Traction During Delivery

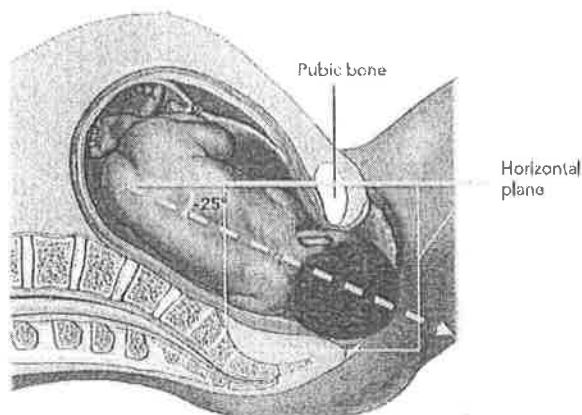


Figure 3-1. Traction applied in the plane of the fetal cervicothoracic spine is typically along a vector estimated to be 25–45 degrees below the horizontal plane when the woman in labor is in a lithotomy position. ↵

Physician traction – a normal component of vaginal delivery – can be separated into two categories: axial traction and lateral bending. *Id.* at 29. During childbirth, the fetal spine is aligned at an angle relative to the delivery table, typically 25 to 45 degrees below the horizontal plane [see Figure 3-1]. Traction applied in axis of the fetal spine is transmitted down the entire spine, similar to how uterine contractions push against the entire fetal body. In contrast, lateral force that pulls the infant head out of axis to one side applies force directly against the neck and brachial plexus. Thus, “[t]he key principle to minimize stretching of the brachial plexus is to avoid lateral bending of the neck—that is, moving the fetus’ head out of alignment with the fetal . . . spine[.]” *Id.*

“For most of the 20th century, it was routinely accepted that NBPP was caused by clinician applied traction during the delivery process, despite an absence of clinical data supporting this contention.” *Id.* at 31. More recent studies in the field emphasize the role played by maternal forces of labor and have distinguished between categories of physician-applied traction during birth, i.e., appropriate gentle downward axial traction as opposed to lateral bending traction.

d. Clinical Studies of Maternal Forces of Labor and Shoulder Dystocia

Numerous scientific studies have concluded that NBPP injury can be caused solely by maternal forces of labor. Large scale retrospective studies conducted from 1990 to 2011 have demonstrated that NBPP injury occurs in about 46% of cases without any clinical documentation of shoulder dystocia. *Id.* at 2, 10-11. As such non-dystocia deliveries would not involve the application of significant physician traction to effectuate delivery, the results strongly suggest that NBPP injuries can be caused by maternal forces alone. *Id.* Further, NBPP injuries have remained relatively constant from the late 1980s, despite later widespread use of the McRoberts' maneuver and other clinical techniques that can reduce physician-applied traction—suggesting that something other than clinician traction is causing NBPP. *See id.* at 31.

Furthermore, numerous case studies have confirmed brachial plexus injuries to a newborn's posterior shoulder, which could only have been caused by maternal forces of labor. As noted, a posterior shoulder during childbirth impacts with the sacral promontory before the fetal head delivers and before the clinician applies any traction, and thus an injury resulting from such an impact occurs at a time when the only forces being applied to the fetus are maternal forces of labor.²⁸ Notably, one of these case studies was co-authored by Plaintiff's expert Dr. Allen.²⁹

²⁸ *See id.* at 27-28; *see also* Exh. 14, Ouzounian et al. "Permanent Erb Palsy: A Lack of Relationship with Obstetrical Risk Factors?," 89 J. Obstetrics & Gynecology 139-141 (1997) ("Findings of brachial plexus injury in the posterior arm of infants with antecedent anterior shoulder dystocia . . . suggest that the brachial plexus injury may well result from in utero events or the normal delivery process and not from traction applied at delivery"); Exh. 15, Sandmire and DeMott, "Erb's Palsy Causation: Iatrogenic or Resulting from Labor Forces," 50 J. Reproductive Med. 563-566 (2005); ("Considerable indirect evidence favors maternal labor forces as the most likely cause of Erb's palsy[.]" including NBPP injuries to a posterior arm).

²⁹ *See* Exh. 16, Allen and Gurewitsch, "Temporary Erb-Duchenne Palsy Without Shoulder Dystocia or Traction to Fetal Head, 105 J. Obstetrics & Gynecology 1210-1212 (2005).

Further, there have been reported instances of a posterior shoulder NBPP when the newborn also had a shoulder dystocia affecting the anterior shoulder.³⁰

In the instant case, there is no clear evidence as to whether B.M.'s left shoulder was anterior or posterior at the time of delivery. The baby's position was not documented in the medical record by any provider, and no provider recalls the position.³¹ As a matter of statistics, a majority of reported NBPP cases involve an anterior shoulder, as several experts in the case acknowledged. But a baby can face in either direction, and both shoulders can be stretched during delivery. In the absence of any evidence about the position of the baby here, it is not possible to state which of B.M.'s shoulders were anterior, and which was posterior at the time of delivery.

Dr. Grimm recognized this critical gap in the evidence and offered causation opinions addressing both potential alternatives. In contrast, Dr. Allen's opinions assume that the left shoulder must have been the anterior shoulder to which "downward lateral traction" must have been applied during delivery—an assumption for which he has offered no adequate basis or foundation.

e. Sophisticated Models of Maternal Forces and Shoulder Dystocia

Because of fundamental ethical concerns, it is impossible to directly examine the biomechanics and causation of brachial plexus injuries in live human neonates, which could put them at risk of injury. However, there is a well-developed scientific consensus that NBPP can be caused by maternal forces of labor, based on physical, animal, and computer models.³²

³⁰ See Exh. 17, Gherman et al. "Brachial Plexus Palsy: An In Utero Injury?" 180 Am. J. Obstet. Gynecol. 1303-1307 (1999).

³¹ See Exh. 5, Dr. Welch Depo at 101 (stating in response to a question as to whether B.M.'s left shoulder was the posterior shoulder, "I can't say one way or another, I don't remember.").

³² Exh. 1, ACOG Monograph, at 24-25.

Dr. Grimm and colleagues have used a sophisticated computer software called MADYMO, designed to model how the human body responds to forces, to develop a model of a mother's pelvis and an infant to study the various forces, both maternal and clinician-applied in play during delivery. The computerized model was created with a degree of specificity and precision that could depict the actual forces present during an actual labor and delivery. Applying that model, Grimm and colleagues found that a substantial amount of stretch to the brachial plexus, estimated at 18.2%, occurs naturally during a shoulder dystocia delivery as a result of maternal forces of labor.³³ In a brachial plexus palsy, the degree of stretch to the nerve is what causes the injury, regardless of the degree of force applied. Even Dr. Allen acknowledges that applied force, whether endogenous or exogenous, does not directly cause nerve injury; rather, forces cause the nerve to stretch.³⁴ Animal studies examining stretch to animal nerve roots have indicated that stretch of 11 – 20% can be sufficient to cause nerve rupture—well within the range of stretch occurring during a shoulder dystocia through maternal forces.³⁵ Dr. Grimm's findings have been cited not only in the ACOG monograph, but also in leading obstetrics textbooks, including for example Gabbe et al.'s *Obstetrics: Normal and Problem Pregnancies*:

Using computer modeling, the forces applied to the fetal brachial plexus during dystocia delivery, and also with the addition of release maneuvers, were estimated by Grimm and colleagues . . . In the past . . . it was believed that brachial plexus injury resulted primarily from operator-induced excess traction in the setting of shoulder dystocia. **Evidence now exists that plexus injuries may result from endogenous forces during the second stage of labor. Shoulder dystocia itself**

³³ Exh. 18, Gonik and Grimm, et al., Prediction of Brachial Plexus Stretching During Shoulder Dystocia Using a Computer Simulation Model, 189 Am. J. Obstetrics & Gynecology 1168-72 (2003); *see also* Exh. 19, Grimm et al., "Effect of Clinician-Applied Maneuvers on Brachial Plexus Stretch During a Shoulder Dystocia Event: Investigation Using a Computer Simulation Model. 203 Am. J. Obstetrics & Gynecology 339 (2010).

³⁴ See Exh. 6, Depo of Dr. Allen, at 51.

³⁵ Exh. 20, Singh A., et al., "Mechanical Properties of Spinal Nerve Roots Subjected to Tension at Different Strain Rates," 39 J. Biomechanics 1669-76 (2006); *see also* Exh. 1, ACOG Monograph, at 35-36 (discussing additional animal studies).

places the brachial plexus on stretch. Maternal endogenous forces may actually exceed clinician-applied exogenous forces as well.³⁶

(Emphasis in original).

III. LEGAL STANDARDS

A. Maryland Substantive Law Controls on Burden of Proof for Medical Negligence and Causation

“[A] federal court, acting under its diversity jurisdiction, must apply the substantive law of the state where the cause of action arose.”³⁷ B.M. was delivered in Maryland, and to recover on a claim that a doctor or hospital’s negligence caused injury under Maryland law, the plaintiff must show that the defendant(s) failed to “exercise the degree of care or skill expected of a reasonably competent health care provider in the same or similar circumstances.”³⁸ Further, the plaintiff must show by a preponderance of the evidence that the negligence more likely than not caused the alleged injury.³⁹ With rare exceptions not applicable here, a plaintiff must produce expert testimony to establish causation.⁴⁰

B. Federal Procedural Law Controls the Admissibility of Expert Testimony

All expert testimony in a medical negligence action in federal court is also subject the procedural requirements of the Federal Rules of Evidence. *Daubert*’s application of Federal Rule of Evidence 702 requires that a district court exercise a gate-keeping role to determine whether the expert opinion “rests on a reliable foundation and is relevant.”⁴¹ Further, “[t]he proponent of the

³⁶ Exh 13, Gabbe et al., *Obstetrics: Normal and Problem Pregnancies*, 409 (6th Ed. 2012).

³⁷ *Davison v. Sinai Hosp. of Baltimore, Inc.*, 462 F. Supp. 778, 779–80 (D. Md. 1978), *aff’d*, 617 F.2d 361 (4th Cir. 1980); *see also Lewis v. Waletzky*, 576 F. Supp. 2d 732, 735 (D. Md. 2008), *aff’d*, 475 F. App’x 906 (4th Cir. 2012).

³⁸ *Davis v. Armacost*, 234 Md. App. 71, 85, 168 A.3d 1112, 1119 (2017) (internal citations omitted).

³⁹ *Fennel v. S. Md. Hosp., Inc.*, 320 Md. 776, 787, 580 A.2d 206 (1990).

⁴⁰ *Rodriguez v. Clarke*, 400 Md. 39, 71, 926 A.2d 736, 755 (2007).

⁴¹ *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 61 (4th Cir. 1999) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167 (1999)); *see also Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996).

expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements are met.”⁴²

ARGUMENT

A. Expert Opinions Must be Scientifically Reliable and Helpful to the Jury

Rule 702 provides that an expert witness may testify only if he or she bases an opinion on sufficient facts or data, utilizes reliable principles and methods, and reliably applies the principles and methods to the facts of the case. Further, the expert testimony must help the trier of fact to understand the evidence or to determine a fact in issue. Dr. Allen’s proffered testimony fails to meet these conditions. Because of the strong influence that expert witnesses can have over a jury, the Supreme Court instructs District Court judges to act as “gatekeepers” so that only reliable and relevant expert testimony reaches the jury.⁴³

1. Expert Opinions Must be Scientifically Reliable

Reliability is the touchstone of any *Daubert* inquiry. Application of reliable scientific methods to facts or data is what separates scientific knowledge from idle speculation.⁴⁴ Under *Daubert*, “the validity of the methodology or reasoning is determined using a flexible inquiry based on five factors: (1) whether the testimony has been tested, (2) whether it has been published or exposed to peer review, (3) its rate of error, (4) whether there are standards and controls over its implementation, and (5) whether it is generally accepted.”⁴⁵

An expert’s assurance that he has used a reliable methodology does not make it so. Indeed, the Supreme Court has repeatedly instructed judges that “nothing in either *Daubert* or the Federal

⁴² *In re Silicone Gel Breast Implants Products Liability Litig.*, 318 F. Supp. 2d 879, 889 (C.D. Cal. 2004).

⁴³ *Daubert*, 509 U.S. at 589, 592 (1993).

⁴⁴ *See McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004) (“[T]he expert testimony must be reliable, so that it must be ‘scientific,’ meaning grounded in the methods and procedures of science, and must constitute ‘knowledge,’ meaning something more than subjective belief or unsupported assumptions.”).

⁴⁵ *Cavallo*, 100 F.3d at 1158 (citing *Daubert*, 509 U.S. at 591-95).

Rules of Evidence requires a district court to admit opinion evidence as connected to existing data only by the *ipse dixit* of the expert.”⁴⁶ Rather, every expert “must demonstrate that the expert’s findings and conclusions are based on the scientific method, and, therefore, are reliable. This requires some objective, independent validation of the expert’s methodology.”⁴⁷

Federal courts frequently apply *Daubert* to a proposed expert’s testimony about the likely cause of a medical condition.⁴⁸ In situations where the scientific community has reached a consensus view, experts generally cannot offer admissible testimony that ignores that consensus or contradicts it. “Many courts have recognized that an unexplained conflict with the generally accepted methodology or theories in a given scientific field can be a basis for excluding proffered expert testimony.”⁴⁹ When faced with expert theories on causation of an alleged injury, “[a]ny theory that fails to explain information that otherwise would tend to cast doubt on that theory is inherently suspect.”⁵⁰ In fact, “if the relevant scientific literature contains evidence tending to refute the expert’s theory, and the *expert does not acknowledge or account for that evidence*, the expert’s opinion is unreliable.”⁵¹

2. Expert Opinions Must Fit the Facts of the Case to be Helpful to the Jury

Rule 702 requires that expert testimony must “assist the trier of fact to understand the evidence or to determine a fact in issue” – a condition that the Supreme Court acknowledged in *Daubert* “goes primarily to relevance.” 509 U.S. at 591. The Court emphasized that “[e]xpert

⁴⁶ *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

⁴⁷ *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc).

⁴⁸ See, e.g., *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194 (4th Cir. 2001); *Westberry*, 178 F.3d 257 (4th Cir. 1999); *Benedi v. McNeil-P.P.C. Inc.*, 66 F.3d 1378 (4th Cir. 1995).

⁴⁹ *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1406 (D. Or. 1996)

⁵⁰ *In re Rezulin Products Liability Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005).

⁵¹ *Id.* (emphasis added); see also *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884-87 (10th Cir. 2005) (when plaintiff’s experts “completely ignored or discounted without explanation” the consensus view of contrary studies their methodology “was not medically or scientifically valid.”).

testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Id.* (internal citations omitted). In other words, there must be an appropriate “fit” between the offered opinion and the facts of the case. “Even a theory that might meet certain *Daubert* factors . . . should not be admitted if it does not apply to the specific facts of the case.”⁵²

a. Expert Opinions That Display an “Analytical Gap” Between the Expert’s Conclusions and the Facts of the Case are Impermissible

When an expert fails to connect his methodology and conclusions to the specific facts of the case, “[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”⁵³ An expert’s conclusory ‘because I say so’ statements are insufficient to bridge such an analytical gap; the Supreme Court has repeatedly instructed judges that “nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence as connected to existing data only by the *ipse dixit* of the expert.”⁵⁴

B. Dr. Allen’s Causation Opinions Do Not Fit the Facts of this Case and Are Not Based on a Reliable and Accepted Methodology

Dr. Allen has failed to seriously consider the maternal forces of labor as a potential cause of B.M.’s injury, and did not “fit” his opinions to the facts of B.M.’s delivery. Dr. Allen’s opinion that B.M.’s injury could only be caused by traction applied by Dr. Welch is contrary to the current consensus of the medical literature and is not well-supported by the articles he cites in his report. Therefore, his opinions are neither helpful to the jury nor reliable and do not meet the threshold for admissibility under FRE 702.

⁵² *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056 (8th Cir. 2000) (footnote omitted).

⁵³ *Gen. Elec. Co. v. Joiner*, 522 U.S. at 146.

⁵⁴ *Kumho*, 526 U.S. at 157 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. at 146).

1. Dr. Allen's Opinion that Dr. Welch Caused B.M.'s Injury is Speculative, Does Not Fit the Facts of This Case, and Is Not Supported by Reliable Literature

In his report, Dr. Allen offers a conclusory and speculative opinion that “Dr. Richard Welch caused BM’s permanent brachial plexus injury by applying downward peak traction far in excess – 7 to 8 times – of that normally used during the head-to-body interval.” Exh. 7, Dr. Allen Report at 5. He concludes without basis, and merely from the existence of NBBP itself, that physician-applied traction is the sole cause of this persistent brachial plexus palsy – a view that contradicts the consensus of the relevant literature and generally accepted science. Further, he draws speculative conclusions about Dr. Welch’s delivery from cadaver and unreliable simulations that suffer from significant design defects and limitations. And in drawing his conclusions, Dr. Allen ignores the child’s low muscle tone and ignores the possibility that the arm that was stretched may have been the posterior arm, which would involve no physician-applied traction at all.

a. Dr. Allen Entirely Fails to Address the Possibility That B.M.’s Injury Was to His Posterior Arm and Thus Was Not Traction-Related

Dr. Allen’s opinion that Dr. Welch caused B.M.’s brachial plexus palsy is based on a speculative assumption that the **anterior** shoulder is the shoulder that developed the brachial plexus palsy. But as he conceded, the medical record reflects only that the left shoulder sustained injury; there is no evidence whether the left shoulder was anterior or posterior. Exh. 6, Dr. Allen Depo. at 63-64. *See also* Exh. 21, Dr. Scott Kozin Depo. at 62-64 (plaintiff’s treating physician expert explaining that his causation opinion is conditioned on the *assumption* that B.M.’s left shoulder was anterior, but conceding “[i]t seems to me that **nobody knows which shoulder was anterior and posterior.**”) (emphasis added).

It is unsurprising that Dr. Allen failed to address the possibility that B.M.’s left arm was posterior, because it entirely rules out his theory that the palsy must have been caused by physician-

applied traction. As noted, a brachial plexus stretch of the posterior shoulder occurs **before** any physician traction during delivery. This has been shown in, among other studies, a case report co-authored by Dr. Allen involving a videotaped delivery where an infant sustained a transient NBPP to the posterior arm with no physician traction applied.⁵⁵ Thus, even under Dr. Allen's own research, if B.M.'s brachial plexus palsy occurred to the posterior shoulder, Dr. Allen's physician traction theory fails to "fit" the facts of this case and will not be helpful to the jury.^{56 57}

Several federal courts, including the Court of Appeals for the Eighth Circuit, have held that when there is evidence that a brachial plexus palsy occurred in a posterior limb, the medical science so strongly supports that the injury was caused solely through maternal forces of labor that any expert opinion to the contrary fails to "fit" the facts of the case and must be precluded from evidence.⁵⁸ This Court should apply those cases and preclude Dr. Allen's testimony that this brachial plexus palsy must have occurred due to physician-applied traction.

b. Dr. Allen Has No Reliable Basis to Conclude that Dr. Welch Applied Downward Lateral Bending Traction

Dr. Allen has no basis, and indeed it is not his role as an expert, to decide as a factual matter that Dr. Welch applied downward lateral force by bending B.M.'s head downwards towards the ground, as opposed to gently pulling downward in alignment with the spine. Indeed, Dr. Allen

⁵⁵ See Exh. 16, Allen and Gurewitsch, "Temporary Erb-Duchenne Palsy Without Shoulder Dystocia or Traction to Fetal Head, 105 J. Obstetrics & Gynecology 1210-1212 (2005) (emphasis added).

⁵⁶ See *Daubert*, 509 at 591; see also *See Cooper*, 259 F.3d at 202 (4th Cir. 2001) ("[I]f an expert utterly fails to consider alternative causes . . . a district court is justified in excluding the expert's testimony.").

⁵⁷ At his deposition, Dr. Allen argued there are documented instances of physician applying upward traction to a posterior limb during delivery. Exh. 6, Dr. Allen Depo. at 90-92. However, there is absolutely no evidence in the record that Dr. Welch applied any upward traction to B.M.'s posterior limb, and Dr. Allen himself concludes otherwise.

⁵⁸ See *Lawrey v. Good Samaritan Hosp.*, 751 F.3d 947, 953 (8th Cir. 2014) (noting that "[a]ll credible evidence before this Court suggests that brachial plexus injuries can and do occur in a fixed percentage of births where the clinician applies no traction. And the fact that this case involves a posterior shoulder dystocia cuts against the relevancy of Plaintiff's experts testifying that because he suffered a permanent brachial plexus injury, [medical provider] acted negligently."); see also *Castro v. United States*, No. 2:15-CV-378-FTM-38CM, 2016 WL 5942354, at *6 (M.D. Fla. Oct. 13, 2016).

acknowledged in his report that Dr. Welch “testified he only applies axial traction.” Exh. 7, Dr. Allen Report at 3. And, at his deposition, Dr. Allen further acknowledged a physician can apply downward axial force, and not lateral bending force, to effectuate delivery. Exh. 6, Dr. Allen Depo. at 54-56, 127-28. Dr. Allen was unable to explain how he could infer or interpolate that, contrary to Dr. Welch’s deposition testimony, Dr. Welch must have applied a lateral bending force.

In the absence of case-specific evidence, Dr. Allen contends that strong lateral traction to the fetal head is needed to produce a brachial plexus injury, and cites to a 1979 French study by Metaizeau, et al. Exh. 7, Dr. Allen Report at 5. However, this cadaver study was designed only to look at the progression of an injury to the brachial plexus by hanging weights of gradually increasing size on fetal cadavers. The study does not show that the gradual application of lateral bending traction is the *only* factor in causing brachial plexus nerve rupture during actual clinical deliveries.⁵⁹ Indeed, at his deposition, Dr. Allen acknowledged that numerous other factors may influence the percentage of stretch to a neonatal brachial plexus, including the direction the force was applied (i.e., lateral vs. axial), the speed of the delivery, the duration of force, the time and force rate that the force was applied, and whether there was rotation of the fetal head. Exh. 6, Dr. Allen Depo. at 51-54. Yet Dr. Allen did not know and did not account for any of these other factors in rendering his opinion. *Id.* Instead he merely assumed that forces were applied in a lateral, downward bending direction – an assumption that renders his opinion unreliable.⁶⁰

Dr. Allen also cites several studies for the proposition that strong lateral traction on the fetal head can cause NBPP. Exh. 7, Dr. Allen Report at 5. Several of the studies cited are decades

⁵⁹ See Exh. 1, ACOG Monograph at 31-32.

⁶⁰ See *Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *8 (S.D.W. Va. Sept. 29, 2014) (where biomechanical expert’s testing on vaginal mesh applied a uniaxial force and “did not account for the multi-directional forces inside of the female pelvis, his opinions about the effect of the mesh once implanted in vivo are unreliable and do not survive *Daubert* scrutiny).

old, with one from the 1800s, and bear little weight in the modern science of NBPP. But more to the point, none of these studies reveal anything as to what type of traction Dr. Welch actually applied—lateral bending or axial. Dr. Allen should not be permitted to make a factual determination that Dr. Welch applied lateral bending traction and present it to the jury as “expert opinion,” despite Dr. Welch’s deposition testimony that he did not and indeed always applies *axial* traction. Instead Dr. Allen simply assumes, ignoring other potential causes, that the stretch of B.M. sustained must have involved lateral traction. There is “simply too great an analytical gap between the data and the opinion proffered” for his opinion to be reliable and relevant to the jury, and it should be precluded from evidence.⁶¹

c. Dr. Allen Has No Reliable Basis to Conclude That Dr. Welch Applied 7 to 8 Times the “Normal” Amount of Peak Traction

Not only does Dr. Allen speculate that any traction must have been qualitatively “excessive,” he creates a multiplication factor to foster the illusion that gentle clinician traction is quantitatively measured. In a conclusory unsupported opinion, Dr. Allen stretches credulity by opining that Dr. Welch applied “7 to 8 times” the amount of traction “normally” used during a head-to-body interval in a shoulder dystocia delivery. Exh. 7, Dr. Allen Report at 5. Although the figures and calculations are tellingly absent from his report, Dr. Allen described at deposition his idiosyncratic method, which involves estimating figures for “normal” and excessive forces from studies that did not reliably account for the forces actually applied by clinicians during a live birth. That methodology fails to meet the standard of reliability mandated by *Daubert*.

⁶¹ *Gen. Elec. Co. v. Joiner*, 522 U.S. at 146. Plaintiffs’ hybrid treating physician expert Dr. Kozin similarly testified that his specific causation opinion was predicated on an assumption that “Doctor Welch applied downward traction to [B.M.]’s head and neck” See Exh. 21, Dr. Scott Kozin Depo. at 63. That assumption is entirely unsupported by the record, and if Plaintiffs fail to establish through admissible evidence that Dr. Welch did in fact apply such traction, summary judgment must be granted in favor of the defense.

i. *Dr. Allen 's Reliance on Unreliable Sensor Gloves Studies*

Dr. Allen derives his estimates of the “normal” amount of forces he alleges clinicians routinely apply in routine deliveries, which he contends is zero to ten pounds, from two sensor glove studies that attempted to measure forces applied during delivery by placing sensors on two or four fingers under the gloves of the delivering physician’s right hand.⁶² However, both studies had inherent design limitations and extremely small sample sizes. The contact forces in the physician’s hand that were measured were not the same as the axial or bending forces actually applied to the fetal head during a real delivery. *Id.* A more recent study by Peisner cited by Dr. Allen criticized this methodology, noting that the sensor gloves results were “an approximation of the force on a head.”⁶³ Further, each of the studies looked at fewer than thirty deliveries from a *single* clinician. Significantly, only four of the deliveries were shoulder dystocia deliveries, with only one transient (not permanent) NBPP occurring (in the 1991 Allen study). Such a miniscule sample size simply cannot show how much force is “normally” applied by reasonable clinicians.

Reliance on these unreliable studies to extrapolate precise numerical values to describe how much force was actually applied during an actual shoulder dystocia delivery in Anne Arundel County in 2013 is improper and contrary to accepted scientific method. But it is clear from Dr. Allen’s deposition that is precisely what he did. Exh. 6, Dr. Allen Depo. at 70-74 (explaining his reliance on the sensor gloves studies in rendering his opinion). Dr. Allen stated that he took the high number of average axial force stated in the sensor gloves studies as sufficient for a “routine”⁶⁴

⁶² Exh. 22, Allen, et al., Risk factors for Shoulder Dystocia: An Engineering Study of Clinician Applied Forces, 77 J. Obstetrics & Gynecology 352-5 (1991); Exh. 23, Poggi et al., “Randomized Trial of McRoberts Versus Lithotomy Positioning to Decrease the Force That is Applied to the Fetus During Delivery,” 191 Am. J. Obstetrics & Gynecology 903-06 (2004).

⁶³ Exh. 24, Peisner, DB, “A Device That Measures the Pulling Force and Vector of Delivering a Baby,” 205 Am. J. Obstetrics & Gynecology 221 e.1 - e.7 (2005).

⁶⁴ “Routine” delivery and “difficult” delivery were not defined. Deliveries were categorized based on subjected assessment of one clinician – a categorization that is highly unreliable.

delivery (10 pounds) and the lowest amount (0 pounds) and assumed, without any basis, that a “routine” delivery generally involves the midpoint between the two figures, or around five pounds of force. *Id.* That methodology is unreliable, has not been subject to peer-review,⁶⁵ and lacks scientific support in the relevant field of biomechanics. Efforts to reproduce his quantitative and qualitative data have been unsuccessful.⁶⁶ Further, the delivery here was a shoulder dystocia delivery, not an ordinary delivery, and therefore the figures for “routine” delivery are not relevant. With an unreliable methodology that does not fit the facts of this case, Dr. Allen’s causation opinion is inadmissible.⁶⁷

ii. Dr. Allen Relies on Nerve Gripping Studies That He Admitted Are Unreliable

Dr. Allen starts his next step with the existence of NBPP this one; from that, he assumes that Dr. Welch (as opposed to all forces combined) applied all force needed to stretch the nerve. Without a solid basis to do so, he next equates 30 percent stretch to 35 pounds of force:

Q Okay. And I just want to make sure I understand all your opinions. **You’re assuming in this case that Dr. Welch applied more than a 30 percent stretch; is that right?**

A Yes.

Q **And he applied 35 to 40 pounds of force, if we’re using your mid point of 5 as the peak average, correct?**

A **Yes. In order to create the minimum of 30 percent stretch, probably more.**

Exh. 6, Dr. Allen Depo. at 127. Dr. Allen’s conclusions are based on assumptions: first, that nerve rupture occurs only when nerves are stretched to 30% or greater, and second, that a 30% stretch equates to a force of at least 35 to 40 pounds. Both assumptions come from two unreliable

⁶⁵ While the articles on which Dr. Allen relies were peer-reviewed, his methodology of deriving a so-called “normal” force based on those articles has not been subject to peer review.

⁶⁶ See Affidavit of Dr. Chauhan, Exh. 11.

⁶⁷ See *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1222 (10th Cir. 2003) (“Under *Daubert*, any step that renders the analysis unreliable ... renders the expert's testimony inadmissible.”).

studies.⁶⁸ A 1997 Russian cadaver study by Kalmin subjected 51 cadavers of fetuses and newborns to a slow constant stretching force on the neck in a tensile machine of 10 mm/min until the nerves ruptured. A 1970 Haftek rabbit nerve study applied similar stretching forces to tibial nerves excised from ten-week old rabbits. However, these studies are of doubtful reliability and accuracy in light of changes and developments in biomechanical techniques. Dr. Allen acknowledged at deposition that the studies examined stretch to the nerves by gripping them, which can cause stretch concentrations that will skew the results of stretch testing if not isolated out. *Id.* at 47-48. Further, such studies can have inaccurate results if the grip on the nerve slips, with any slippage making it appear that the nerve stretched more than it actually did. *Id.* at 48-49.

In light of these limitations, Dr. Allen agreed that the studies did not follow currently accepted biomechanical techniques:

Q Well, the one from Kalmin was in 1997. The one from Haftek was from 1970. So let's look at Kalmin first in 1997. **Does that study follow currently acceptable biomechanical techniques?**

A Well, in 20 years there's been a lot of changes, so probably not

Id. at 47 (emphasis added).

iii. Dr. Allen Relies Upon Unreliable Simulator and Training Mannequin Studies

Dr. Allen also contends that that “most physicians” apply more traction during a shoulder dystocia delivery than in other forms of delivery based on the results of studies involving training simulators or mannequins.⁶⁹ However these simulations “do not directly match the clinical

⁶⁸ See *id.* at 47-50; see also Exh. 25, Kalmin, OV, “The Structural Bases of the Tensile Strength Properties of Nerves,” 111 *Morfologija* 39-43 (1997) (translation) (footnote 33 in Dr. Allen’s report). At his deposition, Dr. Allen also referred to one other 2010 study by “Lee” that he stated, “looked at brachial plexus stretch and rupture.” Exh. 6, Dr. Allen Depo. at 59-60. However, that study is not referenced in his report, and Dr. Allen did not bring a copy of the Lee study to his deposition or provide a citation to defense counsel (despite a request that he do so if he intended to rely on it). *Id.* at 60-62. Therefore, Dr. Allen should not be permitted to rely on it as a basis for his opinion.

⁶⁹ Exh. 7, Dr. Allen Report at 5, 11-12 (footnotes 11 – 16).

environment[.]” and are not a reliable basis to extrapolate the amount of traction actually applied in live deliveries. Exh. 1, ACOG Monograph at 30 (2014). One 1995 study Dr. Allen co-authored (footnote 15 in Dr. Allen’s report) measured force levels using an inanimate mechanical birth simulator⁷⁰ that did not accurately model a real clinical situation because it would not actually deliver and did not allow for axial or rotational movements of the fetus. Further, the level of force clinicians applied to the model was purely subjective and thus may not correspond to the force actually applied during live deliveries.⁷¹

Dr. Allen also cited to a study by Crofts, et al. (footnote 13 in Dr. Allen’s report). While the 2014 ACOG Monograph recognized this study used a “high-fidelity training mannequin in hospitals in the United Kingdom,” *Id.* at 30. Dr. Allen ignored a key finding that the majority of clinicians (72%) applied less than 150 N (33.7 pounds) of force at all points during delivery. Thus, contrary to the conclusions Dr. Allen advances in this case, the study suggests that even during a shoulder dystocia or other “difficult” delivery, the majority of physicians apply force below the threshold he believes is necessary to cause injury of 35 to 40 pounds of force or greater.

Finally, Dr. Allen cites to a 2011 article by Peisner that was merely a “pilot study” study that attempted only to show that the simulator worked as described.⁷² The study did not attempt “to determine a range of [delivery] force due to the many parameters that might affect this.” *Id.* Therefore, the study does not support Dr. Allen’s opinions in the instant case.⁷³

⁷⁰ See Exh. 26, Allen et al., *Simulating Birth to Investigate Clinician-Applied Loads on Newborns*, 17 J. Med. Eng. & Physics 380-84 (1994).

⁷¹ Exh. 1, ACOG Monograph at 30 (2014).

⁷² Exh. 24, Peisner, DB, “A Device That Measures the Pulling Force and Vector of Delivering a Baby,” 205 Am. J. Obstetrics & Gynecology 221 e.1 - e.7 (2005).

⁷³ Dr. Allen also cited two conference papers which he co-authored (footnotes 11 and 12 of Dr. Allen’s report). These non-peer reviewed publications are entitled to little weight.

iv. *There is No Evidence that Dr. Welch Applied Excessive Traction*

Further, even assuming *arguendo* that Dr. Allen's approach has any reliable basis (it does not), there is no evidence or basis from which he can reliably conclude that Dr. Welch applied force in excess of 35 to 40 pounds, or 7 to 8 times what Dr. Allen contends is "normal" in a "normal" delivery. Indeed, Dr. Allen acknowledges in his report that "[t]he only documentary evidence that could possibly provide proof [of excessive lateral traction] is a video of the birth or Dr. Welch documenting it himself," neither of which occurred. Exh. 7, Dr. Allen Report at 9. Dr. Allen's opinion lacks adequate factual basis in the record and fails to satisfy the requirements of *Daubert*.

d. Dr. Allen's Opinion That Most Permanent NBPP Injuries Are Caused by Physician Traction is Contrary to the Current Scientific Consensus

Dr. Allen offers a general opinion that most permanent NBPP injuries are associated with physician lateral traction during shoulder dystocia deliveries. *See* Exh. 7, Dr. Allen Report at 6.⁷⁴ Of course, this opinion would lend no weight to his specific opinion that Dr. Welch caused B.M.'s injury. More significantly, Dr. Allen's opinion directly contradicts the consensus of the 2014 ACOG Monograph that brachial plexus injuries can be caused by either maternal forces of labor

⁷⁴ Dr. Allen contends that studies in the field reflect that "almost all neonatal mechanical brachial plexus injuries are associated with shoulder dystocia deliveries when," he contends, "clinician traction is increased." As previously discussed, Dr. Allen has not shown that physician traction is necessarily increased during shoulder dystocia. Moreover, his conclusion that most NBPP injuries occur during shoulder dystocia has been directly rejected by the 2014 ACOG Monograph, which reviewed twelve peer-reviewed retrospective studies from the U.S. and other Western countries, which collectively reviewed over 1.5 million total births, and concluded that 46% of instances of NBPP occurred without a documented shoulder dystocia. Exh. 1, ACOG Monograph at 2, 10-11 (2014) (*see* table 1-4). Dr. Allen also relies heavily on a 2008 study from Sweden (footnote 7 and 25 in his report). His reliance is misplaced, because the great majority of the deliveries in the study applied fundal pressure, a force that confounds the data. As explained in the ACOG Monograph, "it is not possible to separate out the effect of increased traction from the effect of increased expulsive force induced by the application of fundal pressure." *Id.* at 32. Notably, fundal pressure was not used in the delivery of B.M. and is not routinely used in the U.S. Thus, the Swedish fundal pressure study provides no useful data to assess the amount of force typically used to deliver babies in the United States.

or physician applied forces (specifically downward bending forces). Therefore, even this general opinion lacks the indicia of reliability required by *Daubert* and should be precluded.⁷⁵

2. Dr. Allen's Rebuttal Opinions Against Dr. Grimm and Other Defense Experts Likewise Lack a Reliable Scientific Foundation

Dr. Allen's rebuttal opinions against Dr. Grimm and several of Defendants' other experts suffer from similar flaws. Several of his opinions also contradict the consensus of the relevant scientific community reflected in the ACOG Monographs, or offer standard of care testimony that is prohibited in this action under controlling substantive Maryland law.

a. Dr. Allen's Criticisms of Dr. Grimm's Reliance on Computer Modelling and Animal Studies are Baseless

Dr. Allen criticizes Dr. Grimm's reliance on the computer simulation developed in cooperation with Dr. Gonik on the grounds that it "contradicts clinical observations." See Exh. 7, Dr. Allen Report at 7. But the sources he cites to in support of that criticism, a 1955 lecture by Dr. Morris and a set of forceps studies from the 1950s and 1960s, are inapposite.

Dr. Morris' methods are far removed from modern biomechanical science. He merely exposed several neonatal brachial plexi on cadavers, and visually observed them when "simple traction [was] applied upon the neck[.]" concluding that the brachial plexus visually "remained quite lax." *Id.* at 7. This purely visual observation of a cadaver does not reliably demonstrate anything about the forces to which the fetus is subjected during a live birth. In contrast, the computer model developed by Dr. Grimm and colleagues examined maternal forces pushing on the infant's bottom and pelvis while the shoulder was restrained by bony pelvis, and used

⁷⁵ That Dr. Allen failed to even seriously consider or account for the alternative maternal forces of labor theory also indicates that his opinion lacks a reliable basis. See *In re Rezulin*, 369 F. Supp. 2d at 425.

sophisticated modelling software to account for other factors involved in birth such as rotation and speed of delivery.⁷⁶

Similarly, the forceps studies performed in the 1950s and 1960s are inapposite and unreliable. The forceps studies admittedly did not involve shoulder dystocia births and were not attempting to determine how much lateral traction could be applied before a brachial plexus injury resulted. Instead, the studies involved a retrospective look at a number of forceps births in an effort to try to determine the amount of axial force (not lateral bending force) applied in forceps deliveries where the shoulder was not impacted. The research's conclusion that up to 80 pounds of axial pressure can be applied to a baby whose shoulder is not impacted without a resulting injury is irrelevant to the critical causation issues in this case.

Dr. Allen also criticizes Dr. Grimm's 2003 study on the ground that "no other study has produced similar results and no bioengineering study has cited [Dr.] Grimm's work." Exh. 7, Dr. Allen Report at 7. But Dr. Allen believes that the only two bioengineers working in the field of brachial plexus injuries in neonates are himself and Dr. Grimm. Exh. 6, Dr. Allen Depo. at 101. Thus, his criticism simply means that he has chosen not to cite her work, hardly a reasonable basis to critique it. Moreover, as Dr. Allen acknowledged, Dr. Grimm's work has been cited in a number of other peer-reviewed papers in the field of obstetrics. *Id.* at 102

Dr. Allen's criticism of Dr. Grimm's reliance in her report on a study of adult rat nerves is similarly baseless. Exh. 7, Dr. Allen Report at 8. He does not dispute that Dr. Grimm accurately cited the study's findings that approximately 15% of nerve roots will rupture at between 11 and 20% stretch. And, he both relied on animal nerve studies in his own report, and agreed at deposition that animal studies can provide useful data for human risk assessments. Exh. 6, Dr.

⁷⁶ See Exh. 18, Gonik and Grimm, et al., Prediction of Brachial Plexus Stretching During Shoulder Dystocia Using a Computer Simulation Model, 189 Am. J. Obstetrics & Gynecology 1168-72 (2003).

Allen Depo. at 86-88. Dr. Allen further critiques Dr. Grimm primarily by citing to additional outdated and unreliable studies, that do not provide a sufficiently reliable foundation for his rebuttal opinions. Notably he cites to the 1997 Kalmin cadaver study (footnote 29) and 1970 Haftek study of rabbit tibial nerves (footnote 33). Exh. 7, Dr. Allen Report at 8. As discussed *supra*, these articles applied unreliable methodology that undermines their findings.

b. Dr. Allen's Opinions Criticizing Defendants' Physician Experts Are Unreliable and Impermissible Under Maryland Law

Dr. Allen offers set of conclusory rebuttal opinions regarding the proffered testimony of Defendants obstetrical and maternal-fetal medicine physician experts Craig Dickman, M.D. (OB-GYN expert), Nancy Hammond (OB-GYN), Kenneth Silver, M.D. (pediatric neurology expert), Stephanie Greene, M.D. (neurosurgery expert), and Suneet Chauhan (maternal-fetal medicine). Exh. 7, Dr. Allen Report at 8-10. These opinions lack any scientific or factual basis and are impermissible under *Daubert*. Further, in several instances, he offers opinions relating to the standard of care that as a biomechanical engineer he is not qualified to make.

i. Dr. Allen's Physician Rebuttal Opinions Are Impermissible Under Daubert

Dr. Allen criticizes Drs. Chauhan, Dickman and Hammond's conclusions that there is no evidence that excessive lateral traction was used in this delivery, but then immediately concedes that there is not only no evidence of "excessive" lateral traction, but that there is no evidence that any lateral, downward bending traction was applied. *Id.* at 9. Perplexingly, Dr. Allen also criticizes Dr. Green's conclusion that medical literature supports that brachial plexus injuries can occur without clinician traction. However, Dr. Allen co-authored a case report that described an instance of brachial plexus palsy to the posterior arm without any physician traction being

applied.⁷⁷ Further, as discussed extensively *supra*, the well-recognized and generally accepted ACOG Monograph and literature strongly support maternal forces of labor as well as physician traction as a potential cause of brachial plexus injuries. Likewise, Dr. Allen's criticism of Drs. Greene and Silver's opinion that brachial plexus injury rates have not significantly changed conflicts with the consensus view of the scientific community. Based on retrospective population-level data from 40 studies reviewed in the 2014 ACOG report, the overall incidence of NBPP, both temporary and persistent, is 1.5 per 1,000 total births in the United States. Exh. 1, ACOG Monograph at 1-2. Those studies demonstrate that the injury rate has "varied little in the past 20 years" prior to 2014. *Id.*⁷⁸

ii. Dr. Allen's Rebuttal Opinions Relating to the Standard of Care are Impermissible Under Controlling Maryland Law

Two of Dr. Allen's criticisms of Defendants' experts' opinions address whether or not Dr. Welch's application of traction was excessive from a medical provider's perspective: he chides Drs. Chauhan, Dickman, and Hammond for observing the absence of evidence of excessive lateral traction, and he dismisses Dr. Chauhan's opinion that it is "unimaginable" for a U.S.-trained obstetrician to apply excessive traction in thirty seconds. These are standard of care opinions based on the physician experts' training and experience that enables them to assess what is within the norm for a shoulder dystocia delivery.

⁷⁷ See Exh. 16, Allen and Gurewitsch, "Temporary Erb-Duchenne Palsy Without Shoulder Dystocia or Traction to Fetal Head, 105 J. Obstetrics & Gynecology 1210-1212 (2005).

⁷⁸ Dr. Allen also criticizes Dr. Greene's citation in his deposition to a 2008 case report which, in Dr. Allen's view, is unreliable because the author did not disclose a potential conflict of interest. However, such a criticism is not the kind of testimony that requires expert opinion, and will not be helpful to the jury when inappropriately couched as an expert opinion. *Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cty., Fla.*, 402 F.3d 1092, 1111 (11th Cir. 2005) ("Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments.").

Dr. Allen, a biomedical engineer with no medical training, admits that he is unqualified to offer standard of care opinions. Exh. 6, Dr. Allen Depo. at 36-37. He is also barred from offering such opinions under Maryland law, which imposes significant additional requirements for standard of care expert testimony in a medical malpractice action.⁷⁹ Therefore, Dr. Allen, who is an engineer and not a board-certified physician, should be precluded from offering testimony about the standard of care, even when it masquerades as ‘causation’.

IV. CONCLUSION

Dr. Allen’s opinions contradict and fail to seriously consider the weight of medical literature that show that brachial plexus injuries can be caused by maternal forces of labor, alone or in combination with typically-applied delivery traction. Dr. Allen’s opinions are instead based on speculative and unreliable extrapolations from outdated studies that suffered from significant design limitations, limitations that Dr. Allen fails to address or acknowledge in his report. He and other experts have made factual determinations about the manner in which Dr. Welch delivered the baby (e.g., excessive downward lateral bending) disguised as opinions. And, Dr. Allen did not fit his opinion to the facts of this case, ignoring the significant role of the baby’s low tone at birth, the possibilities that the stretch and palsy may have occurred to his posterior limb, and Dr. Welch’s testimony that he applies only axial traction. Dr. Allen’s opinions also stray into criticisms of the standard of care that he is not qualified to offer.

⁷⁹ Specifically, the Maryland Health Claims Act requires that an expert witness who “testifies in relation to a proceeding before a panel or court concerning a defendant’s compliance with or departure from standards of care . . . [s]hall have had clinical experience, provided consultation relating to clinical practice, or taught medicine in the defendant’s specialty or a related field of health care, or in the field of health care in which the defendant provided care or treatment to the plaintiff,” and also “shall be board certified in the same or a related specialty as the defendant.” Md. Code, Cts. & Jud. Proc. § 3-2A-02(c)(2)(ii). The requirements of the Maryland Health Claims Act are substantive, and not procedural. *See Davison*, 462 F. Supp. at 780 (concluding that the Act was “‘substantive’ for *Erie* purposes”); *see also Lewis*, 576 F. Supp. 2d at 735.

For these reasons, Dr. Allen should not be permitted to offer his speculative and unreliable opinions in this case.

Respectfully submitted,

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REQUEST FOR HEARING

Defendants respectfully request an evidentiary hearing be held on their Motion to Preclude Plaintiffs' Rebuttal Expert Robert Allen, Ph.D.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY, that on this 12th day of March 2018, a copy of Defendants' Motion to Preclude Plaintiffs' Rebuttal Expert Robert Allen, Ph.D. and Supporting Memorandum, request for hearing, and proposed order were caused to be served electronically on all parties:

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